Express Mail Label No. EL517535224US 02/14/00

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UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Docket No.
PHLL-141

Total Pages in this Submission
34

jc572 U.S. PTO 02/11/00

TO THE ASSISTANT COMMISSIONER FOR PATENTS
Box Patent Application
Washington, D.C. 20231

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

SHAPED BIOCOMPATIBLE RADIATION SHIELD AND METHOD FOR MAKING SAME

jc511 U.S. PTO 09/502762 02/11/00

and invented by:

Alan P. Sliski and Kenneth J. Harte

If a CONTINUATION APPLICATION, *check appropriate box and supply the requisite information:*

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Which is a:

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Which is a:

☐ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: _____

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having **18** pages and including the following:
   - a. ☒ Descriptive Title of the Invention
   - b. ☐ Cross References to Related Applications *(if applicable)*
   - c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   - d. ☐ Reference to Microfiche Appendix *(if applicable)*
   - e. ☒ Background of the Invention
   - f. ☒ Brief Summary of the Invention
   - g. ☒ Brief Description of the Drawings *(if drawings filed)*
   - h. ☒ Detailed Description
   - i. ☒ Claim(s) as Classified Below
   - j. ☒ Abstract of the Disclosure

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34

Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
   a. ☐ Formal b. ☒ Informal Number of Sheets 6
4. ☒ Oath or Declaration
   a. ☒ Newly executed *(original or copy)* ☐ Unexecuted
   b. ☐ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
   c. ☒ With Power of Attorney ☐ Without Power of Attorney
   d. ☐ *DELETION OF INVENTOR(S)*
   Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation By Reference *(usable if Box 4b is checked)*
   The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
6. ☐ Computer Program in Microfiche
7. ☐ Genetic Sequence Submission *(if applicable, all must be included)*
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☒ Assignment Papers *(cover sheet & documents)*
9. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)*
10. ☐ English Translation Document *(if applicable)*
11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations
12. ☐ Preliminary Amendment
13. ☒ Acknowledgment postcard
14. ☒ Certificate of Mailing
    ☐ First Class ☒ Express Mail *(Specify Label No.):* EL517535224US

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Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: 1

17. ☐ Additional Enclosures *(please identify below):*

Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra		Rate	Fee
Total Claims	20	- 20 =	0	x	$9.00	$0.00
Indep. Claims	3	- 3 =	0	x	$39.00	$0.00
Multiple Dependent Claims (check if applicable) ☐						$0.00
					BASIC FEE	$345.00
OTHER FEE *(specify purpose)*		Assignment Recordation				$40.00
					TOTAL FILING FEE	$385.00

☒ A check in the amount of **$385.00** to cover the filing fee is enclosed.

☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **50-1133** as described below. A duplicate copy of this sheet is enclosed.

- ☐ Charge the amount of as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **February 11, 2000**

Signature

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Applicant or Patentee: Alan P. Sliski and Kenneth J. Harte Attorney's

Serial or Patent Number: Docket No: PHLL-141

Filed or Issued:

For: SHAPED BIOCOMPATIBLE RADIATION SHIELD AND METHOD FOR MAKING SAME

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9 (f) and 1.27 (b)) -- SMALL BUSINESS CONCERN

I hereby declare that I am

☐ the owner of the small business concern identified below:

☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN Photoelectron Corporation

ADDRESS OF CONCERN 5 Forbes Road

Lexington, Massachusetts 02173

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled:

SHAPED BIOCOMPATIBLE RADIATION SHIELD AND METHOD FOR MAKING SAME

by inventor(s)

Alan P. Sliski and Kenneth J. Harte described in

☒ the specification filed herewith

☐ application serial no. , filed

☐ patent no. ,issued

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9 (d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9 (d) or a nonprofit organization under 37 CFR 1.9 (e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME

ADDRESS

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME

ADDRESS

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING John Crowley

TITLE OF PERSON OTHER THAN THE OWNER Controller

ADDRESS OF PERSON SIGNING Photoelectron Corporation

5 Forbes Road, Lexington, MA 02173

SIGNATURE DATE 2/11/2002

G:\PHL\141\sm.ent.wpd

PHLL-141

APPLICATION

FOR

UNITED STATES LETTERS PATENT

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that **ALAN P. SLISKI, a U.S. citizen residing in LINCOLN, MASSACHUSETTS and KENNETH J. HARTE a U.S. citizen residing in CARLISLE, MASSACHUSETTS** have invented certain improvements in an **SHAPED BIOCOMPATIBLE RADIATION SHIELD AND METHOD FOR MAKING SAME** of which the following description in connection with the accompanying drawings is a specification, like reference characters on the drawings indicating like parts in the several figures.

SHAPED BIOCOMPATIBLE RADIATION SHIELD AND METHOD FOR MAKING SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable

REFERENCE TO MICROFICHE APPENDIX

Not Applicable

BACKGROUND OF THE INVENTION

This invention relates to a miniaturized, programmable radiation source for use in delivering substantially constant or intermittent levels of x-rays to a specified region and, more particularly, to an apparatus for delivering a controlled dose of radiation to a localized volume of tissue, such as a volume of tissue of the human body.

In the field of medicine, radiation is used for diagnostic, therapeutic and palliative treatment of patients. The conventional medical radiation sources used for these treatments include large fixed position machines such as linear accelerators ("LINACs"), smaller transportable radiation delivery machines such as high-dose-rate after loaders, and catheters for low-dose-rate brachytherapy. The current state of the art treatment systems utilize computers to generate complex treatment plans for treating complex geometric volumes.

Typically, these systems apply doses of radiation in order to inhibit the growth of new tissue because it is known that radiation affects dividing cells more than the mature cells found in non-growing tissue. Thus, the regrowth of cancerous tissue in the site of an excised tumor can be

treated with radiation to prevent the recurrence of cancer. Alternatively, radiation can be applied to other areas of the body to inhibit tissue growth, for example the growth of new blood vessels inside the eye that can cause macular degeneration.

Conventional radiation treatment systems, such as the LINAC used for medical treatment, utilize a high power remote radiation source and direct a beam of radiation at a target volume, such as a tumor inside the body of a patient. This type of treatment is referred to as teletherapy because the radiation source is located a predefined distance, typically on the order of one meter, from the target. This treatment suffers from the disadvantage that tissue disposed between the radiation source and the target is exposed to radiation.

An alternative treatment system utilizing a point source of radiation is disclosed in U.S. Patent No. 5,153,900 issued to Nomikos et al., owned by the assignee of the present application, which is hereby incorporated by reference. The system includes a miniaturized, insertable probe capable of producing low power radiation in predefined dose geometries or profiles disposed about a predetermined location. One advantage of this system is that the radiation is applied to treat a predefined tissue volume, without significantly affecting the tissue in adjacent volumes.

A typical use of the described radiation therapy system involves positioning the insertable probe into or adjacent to the tumor or the site where the tumor or a portion of the tumor was removed to treat the tissue adjacent the site with radiation. In order to facilitate controlled treatment of the site, it is desirable to support the tissue portions to be treated at a predefined distance from the radiation source. Alternatively, where the treatment involves the treatment of surface tissue or the surface of an organ, it is desirable to control the shape of the surface as well as the shape of the radiation field applied to the surface.

The treatment can involve the application of radiation, either continuously or intermittently, over an extended period of time. Therefore, it is desirable that the insertable probe be adjustably supported in a compliant manner to accurately position the radiation source with respect to the treated site and accommodate normal minor movements of the patient, such as movements associated with breathing.

Accordingly, it is an object of the present invention to provide an improved system for delivering radiation to a localized region.

SUMMARY OF THE INVENTION

The present invention is directed to a biocompatible radiation shield for use with a radiation applicator system, which is mountable to a radiation source in order to apply a predefined dose of radiation to an area or volume. The radiation applicator system includes an applicator and adapter. The adapter couples the applicator to a radiation source. The applicator includes an applicator shank and an applicator head. The adapter engages the applicator shank at the shank's proximate end and thereby allows coupling of the applicator to the radiation source, when the adapter is coupled to the radiation source. At the opposite and distal end of the applicator shank is the applicator head, which is used for applying a predefined dose of radiation across a surface contour to treat a predefined volume of tissue surrounding a surgical site. Preferably, the applicator head and surface contour coincide such that the surface of the applicator head engages and/or supports the area or volume to be treated and applies a uniform dose of radiation over the area or volume to be treated.

The radiation shield is preferably formed to a predefined shape and size and adapted to be coupled to the applicator head in a predefined location in order to shield predefined portions of the treatment area or volume from radiation or to define the shape of the dose of radiation applied to the treatment area or volume. The biocompatible radiation shield is substantially thin and can be coupled to the surface of the applicator head, forming a thin shielding layer between the applicator head and the area or volume to be treated. The radiation head could also be integral with another material that is disposed, at least in part, over the applicator head or could be integral with the applicator head. The applicator head and shield combination can engage and/or support the area or volume that is shielded from the radiation.

In one embodiment, the radiation source includes an elongated probe and is adapted for producing a predefined radiation dose profile about a predetermined location with respect to the probe. In the this embodiment, the applicator system can also include a low energy radiation filter adapted to surround at least a portion of the probe within the applicator head. The low energy radiation filter serves to reduce the low energy radiation produced by the probe which can damage tissue adjacent the applicator head. The applicator head engages and/or supports the area or volume to be treated, such as the area or volume adjacent the site where a tumor was removed in order to permit the application of radiation to prevent the regrowth of the tumor. The radiation shield can be fastened to any portion of the applicator head that may, during treatment, be adjacent a location (such as a vital organ), in which the application of radiation is undesirable.

Preferably, the applicator system (and radiation shield) are adapted to be mounted to the elongated probe of the radiation source to form a self contained treatment assembly. During the surgical procedure, the treatment assembly including the applicator system and radiation shield and the radiation source can be supported by a carrier system. The carrier system can be adapted to support the treatment assembly in a substantially weightless configuration in order to facilitate positioning by the physician during surgery and to accommodate substantially minor movements by the patient, such as breathing.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects of this invention, the various features thereof, as well as the invention itself, may be more fully understood from the following description, when read together with the accompanying drawings in which:

FIGURE 1A is a diagrammatic exploded view of an applicator system with radiation shield, in accordance with the present invention;

FIGURE 1B is a diagrammatic exploded view of the applicator system and radiation shield of Figure 1A and a prior art radiation source, with the applicator system adapter coupled to the radiation source;

FIGURE 2A is a diagrammatic view of the applicator system with the radiation shield and radiation source of Figure 1B in assembled form;

FIGURE 2B is a diagrammatic view showing a cross-section of the applicator system with the radiation shield mounted to the radiation source of Figure 2A;

FIGURE 3 is a diagrammatic view of the distal end of the applicator portion of the applicator system and the radiation shield of Figure 2B coupled together; and

FIGURE 4 is a diagrammatic cross sectional view of a plurality of applicator system applicators and radiation shields forming part of a kit, in accordance with another aspect of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1A shows an applicator system 10 and a biocompatible radiation shield 60 for applying a dose of radiation to an area to treat a volume of tissue. The applicator system 10 includes an applicator 12 and an adapter 20. Applicator 12 includes a shank 38 and a head 30, wherein head 30 is located at a distal end of shank 38. A proximate end of shank 38 removably engages with adapter 20 to form applicator system 10. Wherein adapter 20 is structured for attaching applicator system 10 to a radiation source (not shown). At the opposite and distal end of applicator shank 38, applicator head 30 is adapted for engaging and conforming a tissue cavity to a desired shape in order to permit the area or volume adjacent the tissue cavity to be treated with a predefined dose of radiation.

The biocompatible radiation shield 60 is fastened to the applicator head 30 in order to shield a portion of the treatment area or volume from the dose of radiation. The shape of the applicator head 30 can be selected to closely approximate the shape of the cavity to be treated and the radiation shield 60 can be formed to conform to the shape or contour of the portion of the applicator head where the radiation shield is to be fastened. The applicator system 10 can also include a low energy filter (not shown) for absorbing or blocking low energy radiation.

Figure 1B shows adapter 20 of application system 10 mounted on a radiation source, such as a radiosurgery system 40. The radiosurgery system 40 includes a housing 42, a barrel 44 and an elongated probe 48. The radiosurgery system 40 is adapted for generating a field of radiation having a predefined dose profile about the distal end of the probe 48. The applicator system 10 is adapted to fit over the probe 48 and the barrel 44 of the radiosurgery system 40.

In the embodiment shown, adapter 20 of the applicator system 10, which is supported by

a carrier system arm 15, includes a circumferential groove 46 and a retaining spring 24 (or O-ring) mounted in groove 46. A portion of spring 24 extends above the surface of the adapter 44 to facilitate engagement of applicator 12 to adapter 20. The proximate end of the applicator shank 38 is adapted to fit over adapter 20 and includes an interior, circumferential groove 22 which is adapted to receive the portion of the spring 24 that extends above the adapter groove 46.

As shown in Figures 2A and 2B, the applicator 12 slidably fits over and couples to adapter 20, which is secured to radiosurgery system 40. When applicator 12 is slid on to adapter 20 spring 24 is compressed by the interior surface of shank 38 and, once groove 22 aligns with spring 24, the spring expands to fill groove 22, thereby securely coupling shank 38 of applicator 12 to adapter 20. Consequently, applicator 12 is secured over probe 48 of the radiosurgery system 40. As a person having ordinary skill will appreciate, other well known coupling methods and mechanisms can be used, for example: a bayonet coupling, a threaded coupling, spring loaded ball bearings and detents, and set screws.

A proximate end of the applicator head 30 is adapted to receive probe 48. As shown in Figure 3, the applicator shank 38 includes an applicator barrel 32 which supports applicator head 30. In one form, applicator head 30 is integral with shank 38, and in other forms applicator head 30 is removable such that any of a number of heads can be used with a given shank. The applicator 12 may further include a low energy radiation filter 34 that is formed from a material that absorbs or blocks low energy radiation produced by the probe 48 in order to prevent adverse effects on tissue adjacent the applicator head 30. The shape of the low energy filter 34 is determined by the output profile of the radiation source in the radiation probe 48. Preferably, the shape of the low energy filter 34 is selected to reduce the low energy radiation produced outside

the applicator head 30 to an acceptable level for the required treatment. For applicator systems with large applicator heads, a low energy filter may not be required because the applicator head may be sufficiently sized to attenuate the low energy radiation.

Preferably, the applicator 12 is formed from a biocompatible material such as Ultem-1000, a polyetherimide available from General Electric Plastics of Schenectady, New York. The shank 38 and barrel 32 are either molded or machined from a single piece of material and the filter 34 and the applicator head 30 can be fixed in place using a biocompatible epoxy (such as Epo-Tek 353-ND available from Epo-Tek of Billerica, MA). The applicator 12 can be formed (such as by molding or machining) from a single piece of material or from several pieces that are fastened together, such as by biocompatible epoxy. Preferably, the low energy filter is formed from an aluminum material. Preferably, the radiosurgery system 40 is a photonradiosurgery system (PRS) available from Photoelectron Corp. of Lexington, Massachusetts.

The biocompatible radiation shield 60 can be formed from any biocompatible, radiation blocking or absorbing material. The biocompatible radiation shield 60 can be formed from a tungsten filled urethane material which can be approximately 60 to 90 percent tungsten by weight. In the preferred embodiment, the biocompatible radiation shield 60 is formed from a tungsten filled urethane material which is approximately 80 percent tungsten by weight. Alternatively, the biocompatible radiation shield 60 can be constructed from any known biocompatible material, such as silicone, polyamides, or polystyrenes, which can be filled with a radiation blocking or absorbing material, such as tungsten, gold, platinum, rhodium, iridium, tantalum or barium oxide. In the preferred embodiment, the tungsten filled urethane is a substantially flexible and is adapted, such as by preforming, to conform to the surface contour of

the applicator head 30. Alternatively, as a person having ordinary skill in the art will appreciate, the biocompatible radiation shield can be formed from a substantially rigid material that is molded or preformed to conform to the surface contour of applicator head 30. In the preferred embodiment, the biocompatible radiation shield 60 is fastened to the surface of applicator head 30 by the natural adhesion of the tungsten filled urethane material. Alternatively, as a person having ordinary skill in the art will appreciate, any known biocompatible method of fastening the biocompatible radiation shield 60 to the surface of the applicator head 30 can be used, for example, biocompatible adhesives, small nails or tacks, and welding or fusing.

In the preferred embodiment, the biocompatible radiation shield 60 is formed from a thin sheet of tungsten filled urethane material by a thermoforming process. The thermoforming process includes heating the sheet of tungsten filled urethane material to a predetermined temperature whereby the sheet material can be shaped to conform to the surface contour of an applicator head 30. The predetermined temperature provides that the material is soft enough to be formed but does not flow or stick to the forming equipment. In the preferred embodiment, the tungsten filled urethane material is heated to 135 degrees centigrade for 45 minutes. The heated material is placed onto a form that shapes the material to conform to the surface contour of the applicator head 30 and cut to a predefined size. The formed, biocompatible radiation shield is allowed to cool at which point it retains a preformed shape which substantially conforms to the surface contour of the form and subsequently the applicator head 30.

Figure 4 shows a kit 50 containing a plurality of applicators 12A - 12D and corresponding shields 60A-60D. The kit also preferably includes an accompanying plurality of adapters 20 (not shown). Each applicator can include a different size and/or shaped applicator

head 30 and a different size and/or shape biocompatible radiation shield 60 as may be used to treat multiple sites. In kit 50, applicator 12A includes a spherical shaped applicator head and biocompatible radiation shield and applicators 12B - 12D include ellipsoidal shaped applicator heads of differing size. Applicator adapter 12B includes a substantially ellipsoidal shaped and contoured biocompatible radiation shield. Applicator adapter 12C includes a substantially ellipsoidal contoured and hour glass shaped biocompatible radiation shield. Applicator adapter 12D includes a substantially ellipsoidal shaped and contoured biocompatible radiation shield which includes a hole.

It is desirable for the radiation dose delivered across the surface of the applicator head to be substantially uniform over substantially its entire surface. For spherical surface applicator heads, this accomplished by selecting a radiation probe that produces a substantially spherical radiation dose profile. One method of producing ellipsoidal radiation dose profiles with ellipsoidal applicator heads is to use the density of the surface applicator material to filter the radiation and modify, for example, a spherical dose profile in order to produce an ellipsoidal dose profile. Where it is desirable to shield a location such as a vital organ from radiation, a biocompatible radiation shield 60 can be fastened to the applicator head in the location adjacent the area to be shielded. In addition, thin slits or small holes can be provided in the biocompatible radiation shield in order to further control or attenuate the dose of radiation applied to an area or volume.

Preferably, during treatment, the radiosurgery system 40 with the attached applicator system 10 is supported by a gimbal mounted support system such as that disclosed in commonly owned U.S. Patent application serial no. _____ (Attorney Docket No. PHLL-130),

which is hereby incorporated by reference. This allows a physician applying treatment to guide the tip of the applicator without having to support the weight of the device for the duration of the treatment.

The above described system can be used to treat the site where a tumor or a portion of a tumor was removed with a predefined dose of radiation. The treatment involves inserting the applicator head with the biocompatible radiation shield fastened in position into the site and delivering a continuous or intermittent dose of radiation to the tissue adjacent the exterior surface of the applicator head. Preferably, the shape of the applicator head is selected to closely match the shape of the excised tumor in order to support the surrounding tissue and provide accurate application of the radiation dose.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. For example, the radiation shield could be made integral with the applicator head, rather than separate. The present embodiments are therefore to be considered in respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of the equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. A biocompatible radiation shield for use with a radiation applicator system for a radiation source, said radiation applicator system including an applicator head defining a surface having a predefined shape and surface contour, said radiation shield comprising:

a substantially thin, biocompatible material, adapted to conform to the shape of at least a portion of the surface contour of said applicator head.

2. A biocompatible radiation shield according to claim 1 wherein said biocompatible material includes at least one radiation blocking or absorbing material chosen from the group including tungsten, gold, platinum, rhodium, iridium, tantalum and barium oxide.

3. A biocompatible radiation shield according to claim 1 wherein said biocompatible material includes at least one material chosen from the group including urethane, silicone polyamides, and polystyrenes.

4. A biocompatible radiation shield according to claim 1 wherein at least a portion of said biocompatible material is adapted to be coupled to said applicator head.

5. A biocompatible radiation shield according to claim 1, wherein the biocompatible radiation shield is formed from a tungsten filled urethane material including approximately 60 to 90 percent tungsten by weight.

6. A biocompatible radiation shield according to claim 5, wherein the biocompatible radiation shield is formed from a tungsten filled urethane material including approximately 80 percent tungsten by weight.

7. A radiation applicator system for use with a radiation source for facilitating the application of a dose of radiation to a volume, said radiation applicator system comprising:

A) an applicator, substantially encasing a radiating probe of said radiation source, said applicator including:

i) a shank having a proximate end and a distal end; and

ii) a head secured to said shank distal end and defining a surface for engaging said area to receive said dose of radiation; and

B) an adapter, including:

i) a first coupler suited for mated engagement with said shank proximate end; and

ii) a second coupler suited for mated engagement with said radiation source; and

C) a biocompatible radiation shield coupled to at least a portion of said head.

8. A radiation applicator system according to claim 7 wherein:

said radiation source includes a housing having an elongated probe extending from said housing and said probe is adapted for producing predefined dose profiles of radiation at a distal

end of said probe; and

said head is adapted for receiving said distal end of said probe whereby radiation produced by said probe can be applied to an area adjacent said surface of said head.

9. A radiation applicator system according to claim 7 wherein said applicator head defines a substantially spherical surface and said biocompatible radiation shield is formed in the shape of at least a portion of said substantially spherical surface.

10. A radiation applicator system according to claim 7 wherein said applicator head defines a substantially ellipsoidal surface and said biocompatible radiation shield is formed in the shape of at least a portion of said substantially ellipsoidal surface.

11. A radiation applicator system according to claim 7 wherein said applicator head defines a substantially cylindrical surface and said biocompatible radiation shield is formed in the shape of at least a portion of said substantially cylindrical surface.

12. A radiation applicator system according to claim 7 further comprising a low energy filter, coupled to said distal end of the radiation applicator, for attenuating low energy radiation emitted from said probe.

13. A radiation applicator system according to claim 7 wherein said shank includes a

fastening element adapted for fastening said applicator to said radiation source at first predefined position with respect to said radiation source.

14. A radiation applicator system according to claim 7 wherein the biocompatible radiation shield is formed from a tungsten filled urethane material including approximately 60 to 90 percent tungsten by weight.

15. A kit for applying radiation to a volume, said kit comprising:

a radiation source adapted for producing a predefine radiation dose profile;

a plurality applicator systems and a corresponding plurality of biocompatible radiation shields, each of said applicator systems including:

A) an applicator, substantially encasing a radiating probe of said radiation source, said applicator including:

i) a shank having a proximate end and a distal end; and

ii) a head secured to said shank distal end and defining a surface for engaging said area to receive said dose of radiation; and

B) an adapter, including:

i) a first coupler suited for mated engagement with said shank proximate end; and

ii) a second coupler suited for mated engagement with said radiation source; and

C) a biocompatible radiation shield coupled to at least a portion of said head.

16. A kit according to claim 15 wherein the applicator head of at least one of the plurality of applicator systems is different in size or shape than the applicator head of at least one of the other applicator systems from the plurality of applicator systems.

17. A kit according to claim 15 wherein at least one of the plurality of radiation shields is different in size or shape than at least one of the other radiation shields.

18. A kit according to claim 15 wherein the applicator head of each of the plurality of applicator systems is different in size or shape than the applicator head of each of the other applicator systems.

19. A kit according to claim 15 wherein each of the plurality of radiation shields is different in size or shape than the other radiation shields.

20. A kit according to claim 15 wherein at least one of said biocompatible radiation shields includes at least one radiation blocking or absorbing material chosen from the group including tungsten, gold, platinum, rhodium, iridium, tantalum, and barium oxide.

ABSTRACT OF DISCLOSURE

A radiation applicator system is structured to be mounted to a radiation source for providing a predefined dose of radiation for treating a localized area or volume, such as the tissue surrounding the site of an excised tumor. The applicator system includes an applicator and an adapter. The adapter is formed for fixedly securing the applicator to a radiation source, such as a radiosurgery system which produces a predefined radiation dose profile with respect to a predefined location along the radiation producing probe. The applicator includes a shank and an applicator head, wherein the head is located at a distal end of the applicator shank. A proximate end of the applicator shank couples to the adapter. A distal end of the shank includes the applicator head, which is adapted for engaging and/or supporting the area or volume to be treated with a predefined does of radiation. The applicator can include a low energy radiation filter inside of the applicator head to reduce undesirable low energy radiation emissions. A biocompatible radiation shield may be coupled to the outer surface of the applicator head to block radiation emitted from a portion of the radiation probe, in order to shield an adjacent location or vital organ from any undesired radiation exposure. A plurality of applicators having applicator heads and radiation shields of different sizes and shapes can be provided to accommodate treatment sites of various sizes and shapes.

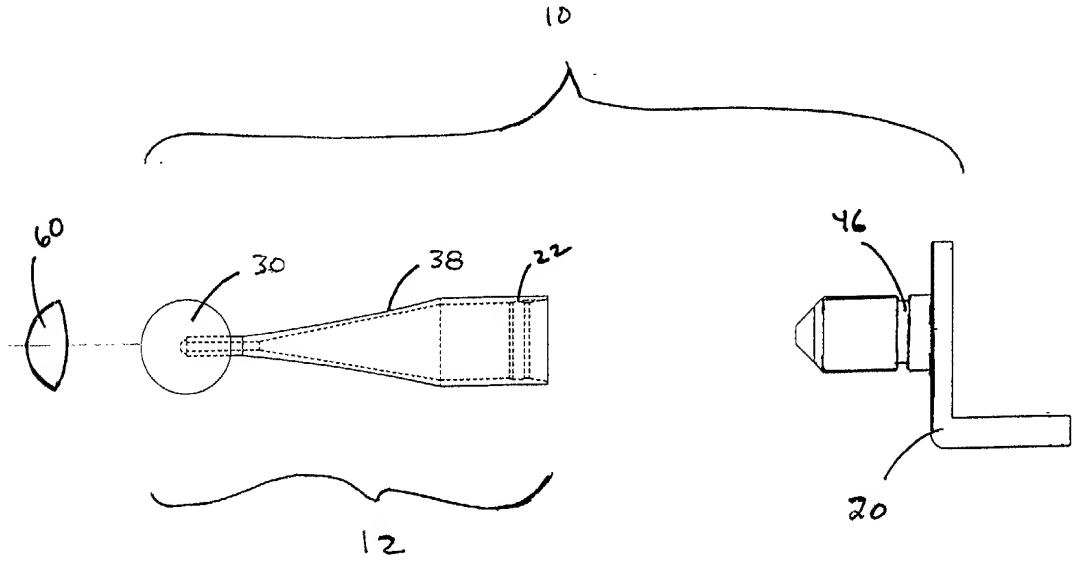

FIG. 1A

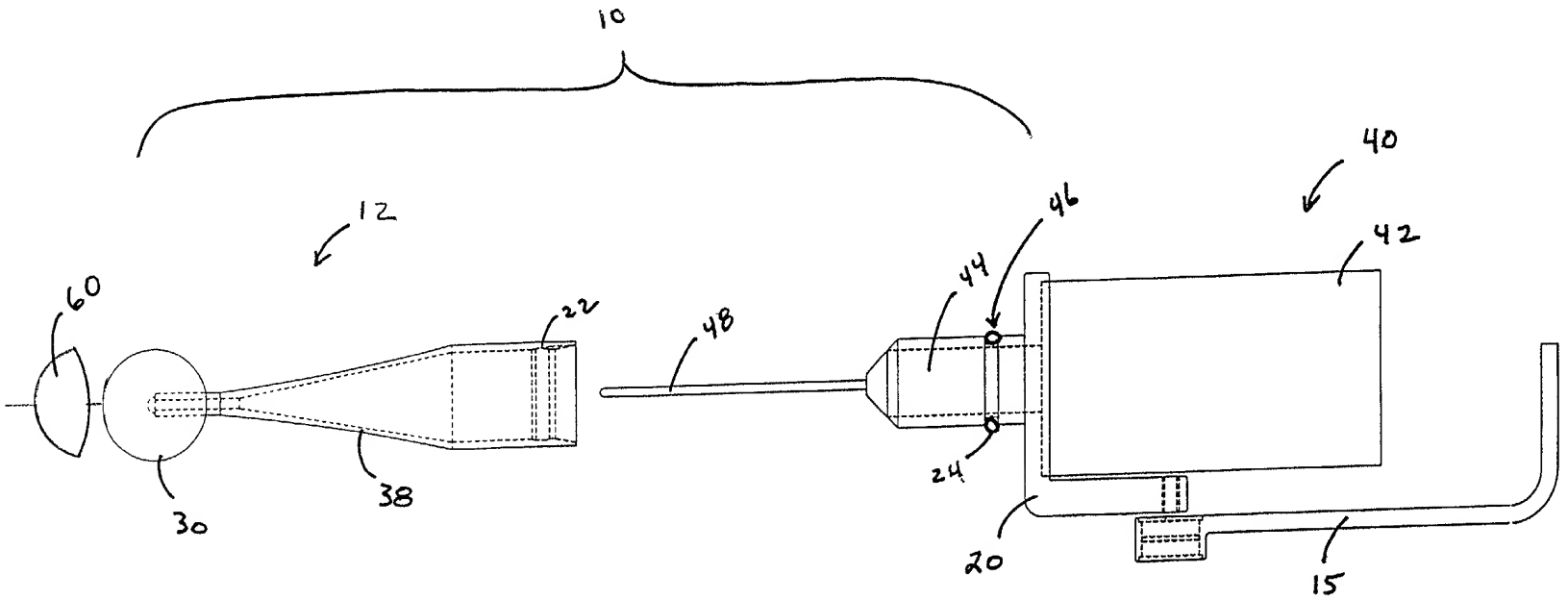

Fig 1B

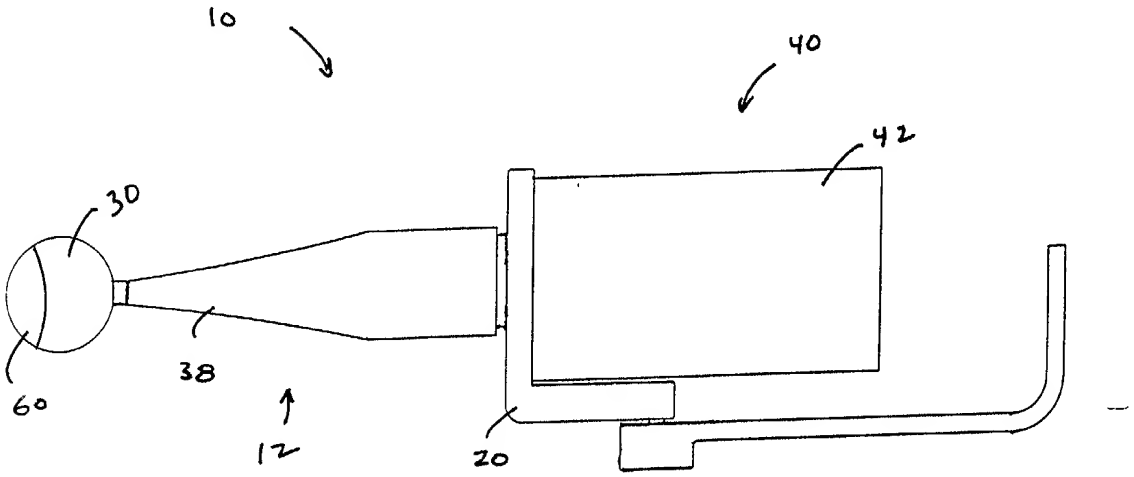

FIG. 2A

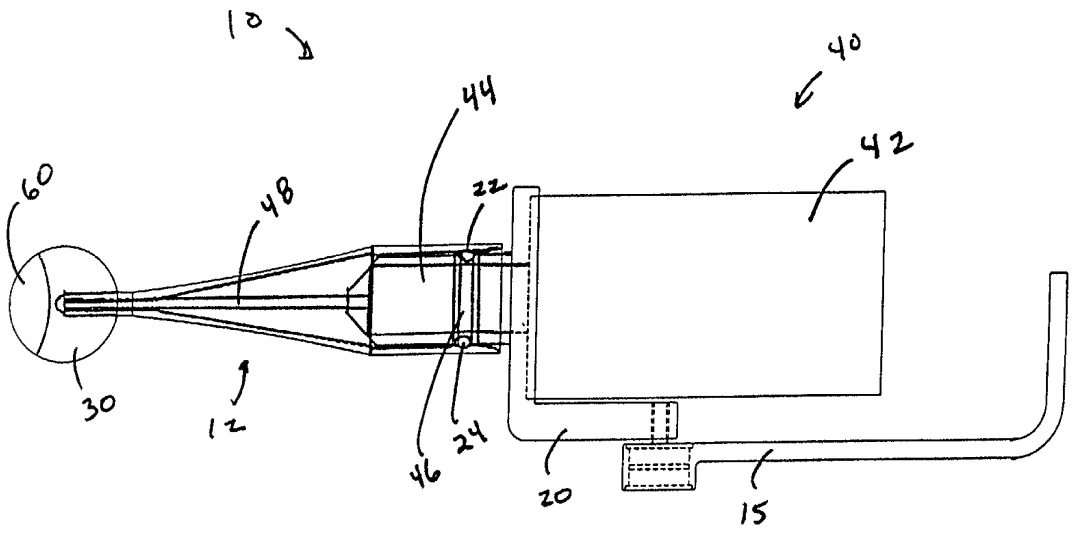

FIG. 2B

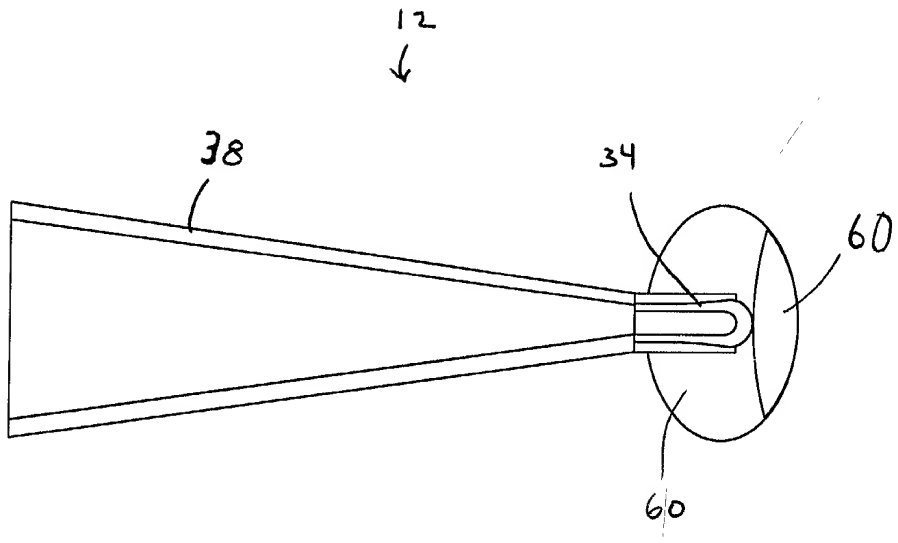

FIG. 3

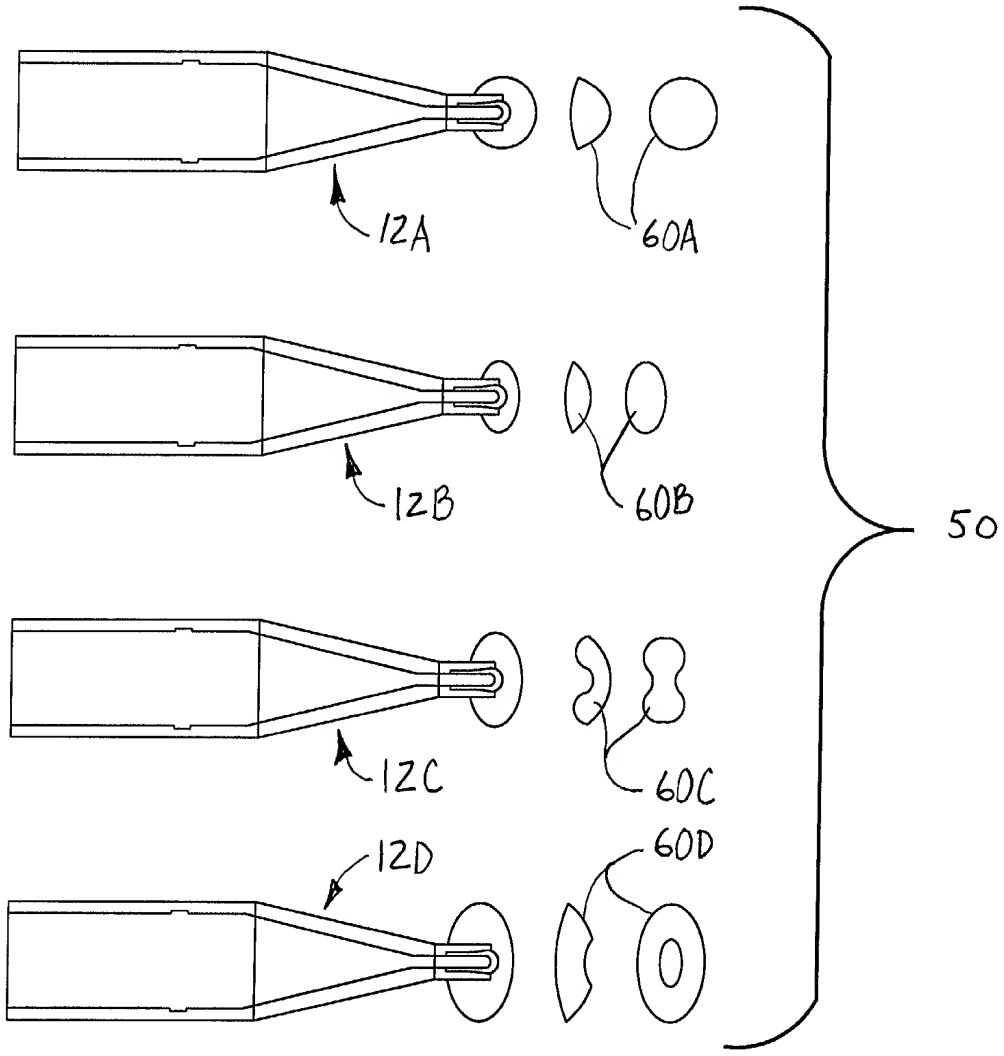

FIG. 4

Docket No.
PHLL-141

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled
SHAPED BIOCOMPATIBLE RADIATION SHIELD AND METHOD FOR MAKING SAME

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International Application Number _____

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
(Number)	(Country)	(Day/Month/Year Filed)	☐
(Number)	(Country)	(Day/Month/Year Filed)	☐
(Number)	(Country)	(Day/Month/Year Filed)	☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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